

No Small Matter: Can TSCA Get Nano Right the First Time?

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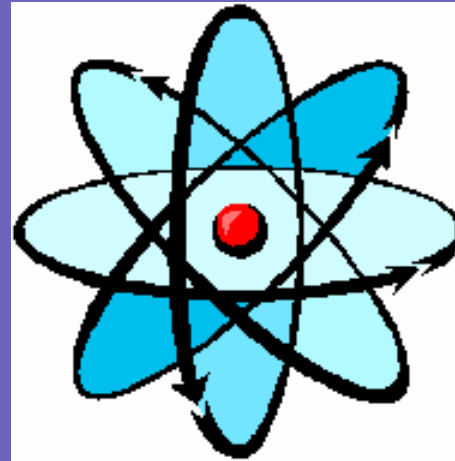
ENVIRONMENTAL DEFENSE

finding the ways that work

Some Key Qs

- When are nanomaterials “new” chemicals that trigger PMNs?
- What data should be included for PMN reviews?
- Do current PMN exemptions make sense?
- What risk-management standards are needed?

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UK Royal Academy of Sciences

“The properties of materials can be **different** at the nanoscale.”

“Nanomaterials have a relatively larger surface area [that] can make materials **more chemically reactive.**”

“**quantum effects** can begin to dominate the behaviour of matter at the nanoscale”

National Nanotechnology Initiative

Three-part definition of nanotechnology

1. Research and technology development at the atomic, molecular or macromolecular levels
2. Creating and using structures, devices and systems that have **novel properties** and functions because of their small and/or intermediate size.
3. Ability to control or manipulate on the atomic scale."

TSCA chemicals

- A chemical substance is “a substance of a particular molecular identity” (sec. 3(2)(a))
 - As distinct from molecular structure or molecular formula



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Novel = new

- An engineered nanoparticle or nanofilm comprised of substances already on the Inventory is being developed precisely *because* it has "novel properties" that differ significantly from those of the conventional material.

Ergo...

- The nanomaterial's molecular identity should be considered "new," regardless of whether its molecular formula or structure is "new"
 - *unless* its chemical and physical properties are demonstrably identical to the conventional substance.

TSCA's Conference Report

“The most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs **before commercial production begins**. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investments is minimized.”

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Data Needs

- Hazard and exposure data sufficient to characterize potential risks:
 - Toxicity (humans, other species)
 - May need new approaches
 - Environmental Fate & Transport
 - Physical/Chemical
 - Use/Exposure
- Existing review models *not* likely adequate

Nano is *different*

“Unlike conventionally produced materials, for which a substantial body of information already exists that EPA can and does use to assess the potential risks of a new chemical based on its structure and function, the novel character of nanomaterials and the dearth of information and experience relevant to assessing their potential risks argues for an information-driven approach at this time.”

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Existing exemptions

- Low volume (annual production below 10,000 kilograms (approximately 22,000 pounds))
- “Low release/low exposure” substances
- Polymers
- No basis to think prior low-risk rationales necessarily fit

Ergo...

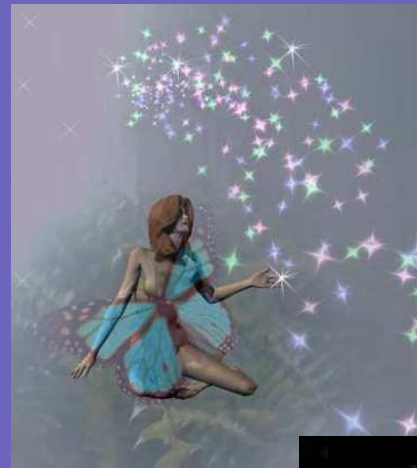
- “Until a sufficient scientific basis is established for setting thresholds appropriate for nanomaterials, such materials should not be eligible for exemptions”

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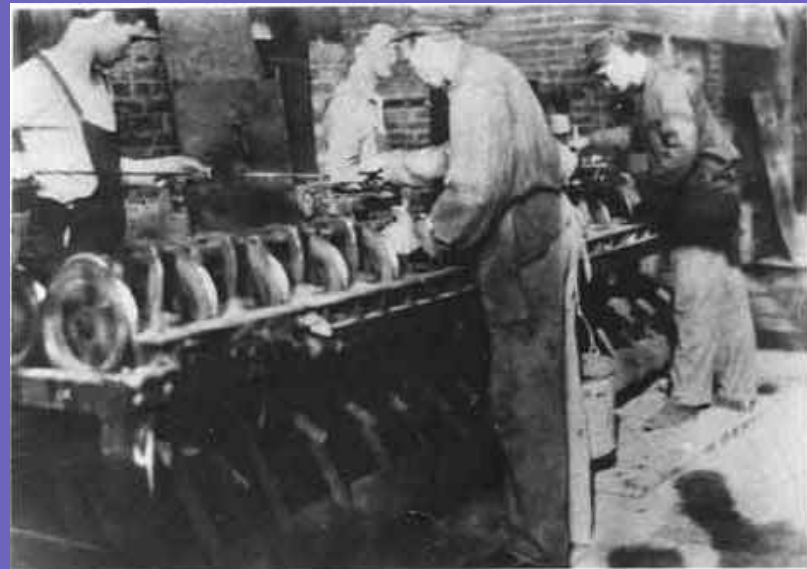
Interim Safety Steps - Environment

- Restrict dispersive uses until hazard and exposure/fate data available
- Assess and disclose lifecycle risks in advance of commercialization
- Release/environmental monitoring



Interim safety steps - workers

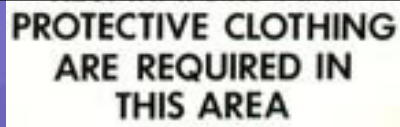
- Assume toxicity until shown otherwise
- Worker training, industrial hygiene, PPE
- Workplace, worker health monitoring
- Wastes treated as hazardous materials



Lest....



\$65B liability costs to insurance industry



\$400M cleanup costs to GE (so far)



\$100M+ in export losses to US farmers (per year)

Some Key Qs - Our Answers

- When are nanomaterials “new” chemicals?
 - Almost always
- What data should be included for PMN reviews?
 - Lots for now
- Do existing PMN exemptions make sense?
 - Some clearly don't
- What risk-management standards are needed?
 - Interim environmental and worker safety measures for now

Bottom line: No “Nano-Loopholes”

